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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,059	08/02/2004	Bernd Stahl	STAH3007/REF	4218

23364 7590 05/11/2009

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EXAMINER	
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ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
05/11/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,059	STAHL ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2008 and 02 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-55* is/are rejected.

7)☒ Claim(s) *43 and 45* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is responsive to Applicant's Amendment and Remarks, filed 29 Dec 2008, in which claims 19-35 are canceled and new claims 36-55 are added, and Applicant's Amendment and Remarks, filed 02 Feb 2009.

The declaration under 37 CFR 1.132 by inventor Bernd Stahl, filed 02 Feb 2009, is acknowledged. The contents of this declaration have been carefully considered and addressed herein.

This application is the 371 national stage entry of PCT/EP03/00505, filed 20 January 2003, claiming benefit of foreign priority document Germany 102 03 999.2, filed 1 February 2002. An English language translation of this foreign priority document is not of record.

Claims 36-55 are pending in the instant application and examined on the merits herein.

Rejections Withdrawn

Applicant's Amendment, filed 29 Dec 2008, with respect to Amended claims 19-32 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the full scope of the claim has been fully considered and is persuasive, as claims 19-32 and 35 are canceled.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 29 Dec 2008, with respect to Amended claims 26, 28 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite has been fully considered and is persuasive, as claims 26, 28 and 29 are canceled.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 29 Dec 2008, with respect to Amended claims 19-32 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Anand et al. (US Patent 5,221,669, provided by Applicant on IDS filed 2 August 2004) has been fully considered and is persuasive, as claims 19-32 and 35 are canceled.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 29 Dec 2008, with respect to Amended claims 19-25, 31 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Roth et al. (WIPO publication WO/90/00596, provided by Applicant on IDS filed 2 August 2004) has been fully considered and is persuasive, as claims 19-25, 31 and 32 are canceled.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 29 Dec 2008, with respect to Amended claims 19-29 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Nelson (US

Patent 6,261,540, of record) has been fully considered and is persuasive, as claims 19-29 and 31 are canceled.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 29 Dec 2008, with respect to Amended claims 19-25, 27-30, 32 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Bernstein (US Patent 4,020,160, of record) has been fully considered and is persuasive, as claims 19-25, 27-30, 32 and 35 are canceled.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 29 Dec 2008, with respect to Amended claims 19-21, 23-25, 28-31 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Bernstein (US Patent 4,020,160, of record) has been fully considered and is persuasive, as claims 19-21, 23-25, 28-31 and 35 are canceled.

This rejection has been **withdrawn**.

Claim Objections

Claim 43 is objected to because of the following informalities: Claim 43 appears to recite the phrase "The method according to claim 36," twice, and claim 43 appears to be identical in scope with claim 38.

Claim 45 is objected to because of the following informalities: the typographical error "composiiton" appears at line 2.

Appropriate correction is required.

The following are new grounds of rejection necessitated by Applicant's Amendment, filed 29 Dec 2008, in which claims 19-35 are canceled and new claims 36-55 are added.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Amended claims 36-55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method using the cycloglycan cyclodextrin, does not reasonably provide enablement for all cycloglycans. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

> (1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: A method for reducing the invasion and infection of mammalian cells by pathogenic, intracellular bacteria to reduce diseases caused by said pathogenic, intracellular bacteria, or in a subject exposed to said pathogenic, intracellular bacteria, comprising administering to a mammal an effective amount of cycloglycans as a fluid or solid food composition, a dietetic composition or a pharmaceutical composition to be administered orally or *per os*.

The state of the prior art: It is known that some cycloglycans may reduce the invasion and infection of mammalian cells by some pathogens. For example, methyl β-cyclodextrin may be used to inhibit infection by the bacterium, *E. coli*. See Duncan et al., page 787, left column, lines 20-23 and right column, lines 45-49 (Cellular Microbiology, 2002, 4, p783-791, of record).

Jutras et al. discloses the use of methyl β-cyclodextrin to prevent invasion of HeLa cells by bacteria of the genus *Chlamydia*. However, internalization of *E. coli* expressing an invasin protein was not significantly impaired by treatment with methyl β-cyclodextrin. See Jutras et al., page 263, left column, lines 29-34 and 52-56 and right column, lines 1-4 (Infection and Immunity, 2003, 71, p260-266, of record).

Roth et al. discloses the use of β-cyclodextrin and derivatives to block HIV-1 entry. Roth et al. disclose the inhibition of infectivity for methyl β-cyclodextrin and β-cyclodextrin with 14 sulfate groups, but no inhibition for propyl β-cyclodextrin or β-cyclodextrin with 4 sulfate groups. See Roth et al., page 25, table 2 (WIPO publication WO/90/00596, provided by Applicant on IDS filed 2 August 2004). While Roth et al. is

drawn to viral infection, Roth et al. shows the pharmacological activity of the cycloglycan cyclodextrin is unpredictable, and varies with the change in substituents.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: As disclosed in the prior art, there is little predictability for which cycloglycans reduce the invasion and infection of mammalian cells by pathogenic, intracellular bacteria. For example, Duncan et al. discloses methyl β-cyclodextrin inhibits infection by the bacterium *E. coli* but does not inhibit invasion by opsonin mediated bacteria. For example, Roth et al. discloses different cycloglycans within the scope of the instant invention as claimed have an unpredictably activity with regard to inhibition of infectivity. This unpredictability, in view of the sheer number of possible cycloglycans and substituents within the scope of the claims means that one skilled in the art cannot predict the usefulness for all possible methods of treatment. Therefore the claimed invention is unpredictable.

The Breadth of the claims: The scope of the claims is infinite. Almost any possible chemical structure could potentially be used as the cycloglycan derivative as disclosed in claim 35 or 53 because, for example, the scope of the claim encompasses a wide scope of monosaccharide, recited substituents, number of recited substituents and substitution pattern.

The amount of direction or guidance presented: The specification speaks generally about cycloglycans that reduce or prevent the invasion and infection of mammalian cells, such as listeria. See specification, page 8, lines 9-14. It is suggested

that "results of the tests conducted clearly show that neither the process of phagocytosis as such, nor the replication of the ingested listeria is inhibited," meaning phagocytosis and replication of listeria is **not** inhibited, and therefore the method of reducing infection and invasion of cells by listeria is **not** disclosed to be enabled. However, guidance is not given for what "the tests" were, or for what cycloglycans may be used to reduce or prevent the invasion and infection of mammalian cells from what pathogens.

The presence or absence of working examples: Working examples are disclosed in declaration under 37 CFR 1.132 by inventor Bernd Stahl, filed 02 Feb 2009. It is noted that all evidence provided is drawn to the cycloglycan cyclodextrin, specifically β-cyclodextrin. At Example 1 at page 7, a cyclodextrin I, II and III is disclosed, however, it is unclear how these numbered cyclodextrins differ from β-cyclodextrin disclosed in pages 2-6.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable art such that involving the pharmacological activity of a genus of cycloglycans. See MPEP 2164. As detailed above, the working examples provided in the declaration are drawn to the cycloglycan cyclodextrin, specifically β-cyclodextrin.

The quantity of experimentation necessary: In order to practice the invention with the full range of all possible methods of reducing or preventing the invasion and infection of mammalian cells by pathogens and combating diseases caused by such pathogens comprising administering to a mammal an effective amount of cycloglycans

beyond those known in the art, (such as methyl β-cyclodextrin) one skilled in the art would undertake a novel and extensive research program into the effectiveness of each cycloglycan. Because this research would have to be exhaustive, and because it would involve such a wide and unpredictable scope of cycloglycans, it would constitute an undue and unpredictable experimental burden.

> *Genentech*, 108 F.3d at 1366, states that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the breadth of the claims, Applicants fail to provide information sufficient to practice the claimed invention for the instantly claimed method using all cycloglycans within the scope of the claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 45 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45 recites "a probe" at line 2. The term renders the claim indefinite because it is unclear what structural limitations are required for a probe. For example, a probe may be a mechanical instrument or a chemical compound. Further, the structure of the probe is dependent on the characteristic to be detected or identified, and no definition of what is being probed is provided. For example, a probe to determine size

may be any object having a physical volume. Therefore one of skill in the art would not be readily apprised of the metes and bounds of the claimed method.

Claim 46 recites the limitation "the composition is a pharmaceutical composition in a form for infusion, oral, lingual, nasal, bronchial, vaginal, topical, or per os administration" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. Claim 36 requires a composition for oral or per os administration, whereas not all lingual, nasal, bronchial, vaginal and topical compositions are compatible with oral or per os administration. Therefore the composition recited in claim 46 is broader in scope than the scope of the claim it depends from.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Amended Claims 36 and 38-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshikumi et al. (US Patent 4,451,457, issued 29 May 1984, cited in PTO-892).

Yoshikumi et al. discloses a method comprising administering α-, β- or γ-cyclodextrin to an animal (abstract) such as a human in order to promote the proliferation of bifidobacteria and thereby reduce intestinal infection (column 1, lines 10-20). Yoshikumi et al. discloses the cyclodextrin in the form of a food, drink and table

luxuries or a pharmaceutical composition (column 4, lines 1-10). It is well known that food comprises protein, carbohydrate biopolymers and fats or lipids, therefore one of skill in the art would readily envision the food carrier comprising a protein, carbohydrate biopolymers or fats or lipids, meeting limitations of instant claim 44. Said food may probe the digestive process of the subject, therefore said food may be interpreted as a probe, meeting limitations of instant claim 45. Yoshikumi et al. discloses said composition administered orally at a dosage of 0.1 to 0.5 g/kg to a man (column 4, lines 30-35). Yoshikumi et al. discloses the agent administered to treat a subject with symptoms of intestinal diseases such as diarrhea or enteritis, diseases well known to be caused by *E. coli*, and discloses the subject exposed to *E. coli* (column 3, lines 50-65), meeting limitations of instant claims 52, 54 and 55. While claim 40 recites further limitations of the β-glycosidically linked monosaccharides, it does not require the cycloglycan to be β-glycosidically linked, therefore the α-glycosidically linked cyclodextrin reads upon claim 40.

Note that activity against *Listeria* or *Salmonella*, recited in instant claims 50 and 51, is merely considered to be new function of a treatment, comprising administering α-, β- or γ-cyclodextrin to an animal such as a human in order to promote the proliferation of bifidobacteria and thereby reduce intestinal infection. It has been settled that the claiming of a new function which is inherently present in the prior art method will not make the claim patentable as set forth in the 102(b) rejection above.

That applicant may have determined a new function of the active ingredient gives the pharmacological effect does not alter the fact that the compound has been

previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, condition to be treated and the effect are the same. Thus, the method steps in Yoshikumi et al. are the same as the method claimed herein. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims. Mere recognition of latent properties in the prior art does not render novel or nonobvious an otherwise known invention. See *In re Wiseman*, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145. It is noted that because there is no nexus connecting the patient population treated by the active step of the instantly claimed method and the pathogenic bacteria *Listeria* or *Salmonella*, therefore the patient populations of the instantly claimed method and that disclosed by Yoshikumi et al.

Amended claims 36-51 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Anand et al. (US Patent 5,221,669, provided by Applicant on IDS filed 2 August 2004). Evidence of inherency is provided by Yoshikumi et al. (US Patent 4,451,457, issued 29 May 1984, cited in PTO-892).

Anand et al. discloses the α-cyclodextrin (CD) sulfate used to treat a viral infection, particularly HIV-1 or HIV-2, by administering α-cyclodextrin sulfate to a patient. See Anand et al., column 3, lines 1-21. HIV is a pathogenic virus that infects

mammalian cells of the blood system, therefore one of skill in the art would have reasonable expectation of activity regarding mammalian cells of the blood system, meeting limitations of instant claim 48. Anand et al. discloses practicing the invention using other cyclodextrin derivatives, for example hydroxypropyl α-CD sulfate and hydroxypropyl β-CD sulfate. See Anand et al., column 5, lines 6-8. Cyclodextrin is a cycloglucan composed of 6 (α-CD), 7 (β-CD), or 8 (γ-CD) glucose units linked by α(1-4) glycosidic bonds. See definition of cyclodextrin (The Merck Index, of record). Anand et al. discloses the α-CD sulfate in a pharmaceutical composition, for example in the form of an oral preparation including binders such as cellulose, starch, and gelatin. See column 10, lines 18-29. Said carrier may probe the treatment volume of the subject, therefore said carrier may be interpreted as a probe, meeting limitations of instant claim 45. Anand et al. discloses, "the actual dose and schedule for drug administration for each patient will vary depending upon interindividual differences in pharmacokinetics, drug disposition and metabolism. Moreover, the dose may vary when the compounds are used prophylactically or when used in combination with other drugs. Such dosage amounts can be readily ascertained without undue burden and experimentation by those skilled in the art. As an example of an antiviral effective amount, the parenteral dosage for humans can range from about between 0.01 mg/kg body weight to 1200 mg/kg body weight." See Anand et al., column 11 lines 36-48 and column 12, lines 1-2. Given this disclosure, one of skill in the art would immediately envision, for example, a dosage of 1200 mg/kg body weight administered once daily. While claim 40 recites further limitations of the β-glycosidically linked monosaccharides, it does not require the

cycloglycan to be β-glycosidically linked, therefore the α-glycosidically linked cyclodextrin reads upon claim 40. Yoshikumi et al. provides evidence that humans are necessarily exposed to the pathogenic, intracellular bacteria *E coli*, therefore the method inherently meets the required treatment population of instant claim 53.

Note that "reducing the invasion and infection of mammalian cells by pathogenic, intracellular bacteria to reduce diseases caused by said pathogenic, intracellular bacteria", or "in a subject exposed to said pathogenic, intracellular bacteria", recited in instant claims 36 and 53, or activity against *Listeria* or *Salmonella*, recited in instant claims 50 and 51 is merely considered to be new function of a treatment, comprising administering a cyclodextrin to patient at the same dosage. It has been settled that the claiming of a new function which is inherently present in the prior art method will not make the claim patentable as set forth in the 102(b) rejection above.

That applicant may have determined a new function of the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects which would result from the claimed method. The patient The patient, dosage and route of administration are the same. Thus, the method steps in Anand et al. are the same as the method claimed herein. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims. Mere recognition of latent properties in the prior art does not render novel or nonobvious an otherwise known invention. See *In re Wiseman*, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which

is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145. It is noted that because there is no nexus connecting the patient population treated by the active step of the instantly claimed method and the pathogenic bacteria *Listeria* or *Salmonella*, therefore the patient populations of the instantly claimed method and that disclosed by Anand et al.

Amended claims 36-43, 46, 48-51 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Roth et al. (WIPO publication WO/90/00596, provided by Applicant on IDS filed 2 August 2004). Evidence of inherency is provided by Yoshikumi et al. (US Patent 4,451,457, issued 29 May 1984, cited in PTO-892).

Roth et al. discloses using a carbohydrate to block cell to cell transmission of a virus, HIV. See Roth et al., page 9, lines 15-19. Roth et al. discloses the use of α-, β-, and γ-CD, possibly derivatized at the C-2, 3, and 6 OH groups of the constituent sugars of the CD. See page 10, lines 7-10 and 17-19. Cyclodextrin is a cycloglucan composed of 6 (α-CD), 7 (β-CD), or 8 (γ-CD) glucose units linked by α(1-4) glycosidic bonds. See definition of cyclodextrin (The Merck Index, of record). Roth et al. discloses the specific CDs of β-CD, β-CD with 4 sulfate groups, β-CD with 4 propoxy groups, and β-CD with 14 sulfate groups. See Roth et al., page 24, lines 24-29. Roth et al. discloses the administration of the carbohydrate to cells within the body of a mammal by several routes of administration, for example the oral route. See Roth et al, page 15, lines 15-21. While claim 40 recites further limitations of the β-glycosidically linked

monosaccharides, it does not require the cycloglycan to be β-glycosidically linked, therefore the α-glycosidically linked cyclodextrin reads upon claim 40. Yoshikumi et al. provides evidence that humans are necessarily exposed to the pathogenic, intracellular bacteria *E coli*, therefore the method inherently meets the required treatment population of instant claim 53.

Note that "reducing the invasion and infection of mammalian cells by pathogenic, intracellular bacteria to reduce diseases caused by said pathogenic, intracellular bacteria", or "in a subject exposed to said pathogenic, intracellular bacteria", recited in instant claims 36 and 53, or activity against *Listeria* or *Salmonella*, recited in instant claims 50 and 51 is merely considered to be new function of a treatment, comprising administering a cyclodextrin to patient at the same dosage. It has been settled that the claiming of a new function which is inherently present in the prior art method will not make the claim patentable as set forth in the 102(b) rejection above.

That applicant may have determined a new function of the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, dosage and route of administration are the same. Thus, the method steps in Roth et al. are the same as the method claimed herein. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims. Mere recognition of latent properties in the prior art does not render novel or nonobvious an otherwise known invention. See *In re Wiseman*, 201 USPQ 658 (CCPA 1979). Granting a patent on the

discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145. It is noted that because there is no nexus connecting the patient population treated by the active step of the instantly claimed method and the pathogenic bacteria *Listeria* or *Salmonella*, therefore the patient populations of the instantly claimed method and that disclosed by Roth et al.

Amended claims 36-44, 46 and 48-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Nelson (US Patent 6,261,540, of record).

Nelson discloses a method of treating oral infections by administering to a mammal an oral composition hydroxypropyl β-CD (abstract and column 3, lines 32-36), meeting limitations of instant claim 19. Nelson discloses that the invention is for the treatment of bacterial infections in the mouth (column 1, lines 52-54), meeting limitations of instant claim 19. The mouth is a respiratory passage, meeting limitations of instant claim 31. Nelson discloses that the composition comprises hydroxypropyl β-CD or hydroxypropyl γ-CD (column 5, lines 11-20), meeting limitations of instant claims 20-26. Cyclodextrin is a cycloglucan composed of 6 (α-CD), 7 (β-CD), or 8 (γ-CD) glucose units linked by α(1-4) glycosidic bonds. See definition of cyclodextrin (The Merck Index, of record). Hydroxypropyl β-CD is a cycloglycan wherein one or more of the OH groups of one or more of the monosaccharides forming the ring is derivatized in the form of an ether. Nelson discloses the oral pharmaceutical composition of a dental rinse with a

carrier or binder, for example cellulose (column 7, lines 16-19 and 44-48), a biopolymer, meeting limitations of instant claim 27. Said carrier may probe the treatment volume of the subject, therefore said carrier may be interpreted as a probe, meeting limitations of instant claim 45. While claim 40 recites further limitations of the β-glycosidically linked monosaccharides, it does not require the cycloglycan to be β-glycosidically linked, therefore the α-glycosidically linked cyclodextrin reads upon claim 40.

Note that "reducing the invasion and infection of mammalian cells by pathogenic, intracellular bacteria to reduce diseases caused by said pathogenic, intracellular bacteria", or "in a subject exposed to said pathogenic, intracellular bacteria", recited in instant claims 36 and 53, or activity against *E. coli*, *Listeria* or *Salmonella*, recited in instant claims 49-51 is merely considered to be new function of a treatment, comprising administering a cyclodextrin to the same patient population by the same route of administration at an effective dosage. It has been settled that the claiming of a new function which is inherently present in the prior art method will not make the claim patentable as set forth in the 102(b) rejection above.

That applicant may have determined a new function of the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, dosage and route of administration are the same. Thus, the method steps in Nelson are the same as the method claimed herein. Mere recognition of latent properties in the prior art does not render novel or nonobvious an otherwise known invention. See *In re Wiseman*, 201 USPQ 658 (CCPA 1979). Granting

a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145. It is noted that because there is no nexus connecting the patient population treated by the active step of the instantly claimed method and the pathogenic bacteria *Listeria* or *Salmonella*, therefore the patient populations of the instantly claimed method and that disclosed by Nelson.

Amended claims 36-51 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Bernstein (US Patent 4,020,160, of record). Evidence of inherency is provided by Yoshikumi et al. (US Patent 4,451,457, issued 29 May 1984, cited in PTO-892).

Bernstein discloses the use of cyclodextrin sulfate salts, α-CD polysulfate, β-CD polysulfate, and γ-CD polysulfate, (column 3, lines 1-8) used to treat inflammatory states induced by bacterial enzymes (column 4, lines 1-3), meeting limitations of instant claims 36-43. This use is to combat a disease caused by invasive bacterial pathogens. Cyclodextrin is a cycloglucan composed of 6 (α-CD), 7 (β-CD), or 8 (γ-CD) glucose units linked by α(1-4) glycosidic bonds, See definition of cyclodextrin (The Merck Index, of record). Cyclodextrin sulfate is a cycloglycan wherein one or more of the OH groups of one or more of the monosaccharides forming the ring is substituted by a sulfate group, meeting limitations of claims 36 and 37. Bernstein discloses the CD used as a composition such as an oral composition, for example with the carrier corn starch, a

biopolymer, for oral administration (column 7, lines 27-29, 53-57, and 64), meeting limitations of instant claims 36, 44 and 46. Said carrier may probe the treatment volume of the subject, therefore said carrier may be interpreted as a probe, meeting limitations of instant claim 45. Bernstein discloses the CD administered at a dose of 5-50 mg/kg/day (column 7, line 39), meeting limitations of instant claim 47. Oral administration will necessarily treat mammalian cells in the gastrointestinal tract, meeting limitations of instant claim 48. While claim 40 recites further limitations of the β-glycosidically linked monosaccharides, it does not require the cycloglycan to be β-glycosidically linked, therefore the α-glycosidically linked cyclodextrin reads upon claim 40. Yoshikumi et al. provides evidence that humans are necessarily exposed to the pathogenic, intracellular bacteria *E coli*, therefore the method inherently meets the required treatment population of instant claim 53.

Note that "reducing the invasion and infection of mammalian cells by pathogenic, intracellular bacteria to reduce diseases caused by said pathogenic, intracellular bacteria", or "in a subject exposed to said pathogenic, intracellular bacteria", recited in instant claims 36 and 53, or activity against *Listeria* or *Salmonella*, recited in instant claims 50 and 51 is merely considered to be new function of a treatment, comprising administering a cyclodextrin to patient at the same dosage. It has been settled that the claiming of a new function which is inherently present in the prior art method will not make the claim patentable as set forth in the 102(b) rejection above.

That applicant may have determined a new function of the active ingredient gives the pharmacological effect does not alter the fact that the compound has been

previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, route of administration, dosage and the effect are the same. Thus, the method steps in Bernstein are the same as the method claimed herein. Mere recognition of latent properties in the prior art does not render novel or nonobvious an otherwise known invention. See *In re Wiseman*, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145. It is noted that because there is no nexus connecting the patient population treated by the active step of the instantly claimed method and the pathogenic bacteria such as *Listeria* or *Salmonella*, therefore the patient populations of the instantly claimed method and that disclosed by Bernstein.

Amended claims 36, 38-43, 46-51 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Castro Hermida et al. (Parasitol. Res., 2001, 87, p449-452, of record). Evidence of inherency is provided by Yoshikumi et al. (US Patent 4,451,457, issued 29 May 1984, cited in PTO-892).

Castro Hermida et al. disclose the use of β-CD to reduce Cryptosporidium infection in the murine model. See Castro Hermida et al., page 449, abstract. Castro Hermida et al. disclose the pharmaceutical composition of the β-CD in sterile water delivered orally to mice. See Castro Hermida et al., page 450, left column, lines 50-53. The infection is an intestinal tract infection. See Castro Hermida et al., page 450, right

column, lines 24-27. The dose administered is 34 mg/kg body weight, administered once daily for the one day of the experiment, and its use in the treatment of disease is suggested. See Castro Hermida et al., page 451, β-CD entry on table 2 and left column, lines 23-30 and right column, lines 16-18. While claim 40 recites further limitations of the β-glycosidically linked monosaccharides, it does not require the cycloglycan to be β-glycosidically linked, therefore the α-glycosidically linked cyclodextrin reads upon claim 40. Yoshikumi et al. provides evidence that mice are necessarily exposed to the pathogenic, intracellular bacteria *E coli*, therefore the method inherently meets the required treatment population of instant claim 53.

Note that "reducing the invasion and infection of mammalian cells by pathogenic, intracellular bacteria to reduce diseases caused by said pathogenic, intracellular bacteria", or "in a subject exposed to said pathogenic, intracellular bacteria", recited in instant claims 36 and 53, or activity against *Listeria* or *Salmonella*, recited in instant claims 50 and 51 is merely considered to be new function of a treatment, comprising administering a cyclodextrin to patient at the same dosage. It has been settled that the claiming of a new function which is inherently present in the prior art method will not make the claim patentable as set forth in the 102(b) rejection above.

That applicant may have determined a new function of the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, route of administration and dosage are the same. Thus, the method steps in Castro Hermida et al. are the same as the method claimed herein.

Mere recognition of latent properties in the prior art does not render novel or nonobvious an otherwise known invention. See *In re Wiseman*, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145. It is noted that because there is no nexus connecting the patient population treated by the active step of the instantly claimed method and the pathogenic bacteria such as *Listeria* or *Salmonella*, therefore the patient populations of the instantly claimed method and that disclosed by Castro Hermida et al.

Conclusion

No claim is found to be allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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